REMARKS

Claim Amendments

The three independent claims, claims 1, 12, and 25, have been amended to add the limitation that the dressing is a gel at body temperature as described at page 6, lines 19-20 of the specification as originally filed.

Claim 12 has been amended to recite that the wound dressing is suitable for inhibiting the occurrence of alveolar osteitis and pain following tooth extraction or jaw cyst removal as described at page 4, lines 19-21 of the of the specification as originally filed.

Claim 29 has been cancelled.

35 U.S.C. § 112, First Paragraph

Claims 1-10, 12-14, 16-20 and 25-29 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Office Action contends that there is no disclosure of 37°C in the disclosure. The Applicant respectfully disagrees. At page 6, lines 19-20 of the specification as originally filed it states: "Thermal stabilization of atelocollagen into a slowly soluble gel at body temperature can be achieved using non-cytotoxic cross linking agents by the following method." (Underlining added.) It is well known that body temperature is 37°C.

It is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

35 U.S.C. § 112, Second Paragraph

Claims 1-10, 12-14, 16-20 and 25-29 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 12 has been amended to make it clear that claim 12 is a

product claim. It is submitted that the rejection under 35 U.S.C. § 112, second paragraph has been overcome by amendment.

35 U.S.C. § 102(b) Rejection

Claims 12-13 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren"). The Office Action states that the "Examiner cannot find where the [Berggren] reference states the disclosed material cannot be a gel below 38 degrees Celsius."

Looking at Berggren, column 4, lines 39-49 read as follows:

> The method of the present invention is particularly useful to heat high-viscosity oligomer or polymer formulations so that the viscosity drops in response to heating and softens to produce a flowable, injectable formulation which returns to its higher viscosity upon cooling to the temperature of the biological pocket. The formulation cools to a more viscous consistency with sufficient cohesiveness to be retainable in the biological pocket (possibly with the addition of a biocompatible adhesive), unlike gels or solutions or other fluids. (Underlining added).

Thus, in the biological pocket, the Berggren material is unlike gels. It is noted that The American Heritage Dictionary of the English Language, Fourth Edition, 2006 defines unlike as "Not alike; different". Thus, below 38 degrees Celsius, the Berggren material is different from a gel. In contrast, amended claim 12 states that the dressing is a gel at body temperature. Thus, the Applicant's claimed invention is substantially different than what is disclosed in Berggren.

It is well settled that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Therefore, it is submitted that the rejection of claims 12-13 and 18 under 35 U.S.C. § 102(b) in view of Berggren has been overcome by amendment.

35 U.S.C. § 103(a) Rejections

Claims 1-2, 4-6, 8-9, 16, 19, 25-26, and 28-29 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren").

Claims 7 and 17 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren") in further view of U.S. Patent No. 6,509,031 to Miller, *et al.* ("Miller").

Claims 3, 10, 14, and 20 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren") in further view of U.S. Patent No. 4,906,670 Higashi, *et al.* ("Higashi").

As detailed above, amended independent claims 1, 12 and 25 now state that the dressing is a gel at body temperature. Regarding the Berggren reference, it was pointed out above that the Berggren material is not a gel at body temperature.

Turning now to Friedman, column 7, lines 20-23 state that "When dried to produce the implants of the present invention, such compositions must have a high enough concentration of protein to produce a non-gel-like material having structural stability." (Underlining added). Thus, the Friedman dressing is not a gel.

Accordingly, it is submitted that Berggren and Friedman do not teach or suggest all of the claim limitations of amended independent claim 1 (and claims 2-10 that depend thereon) or amended independent claim 12 (and claims 13-14 and 16-20 that depend thereon) or amended independent claim 25 (and claims 26-29 that depend thereon). It is well settled that in order to

establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Furthermore, M.P.E.P. § 2143.01 VI. states that a proposed modification cannot change the principle of operation of a reference. Specifically, it is stated that:

> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

It is respectfully submitted that the proposed combination of Friedman with Berggren would change the principle of operation of Friedman such that the teachings of Friedman in view of Berggren are not sufficient to render amended independent claims 1 and 12 and 25 *prima facie* obvious.

At column 4, lines 15-32 of Friedman, the principle of operation of the Friedman device is explained as follows:

> "The sustained-release pharmaceutical compositions of the present invention are polymeric solids which may be cast as an essentially two-dimensional film or as a bullet-shaped (i.e. a torpedo shaped rod or ovoid). The equivalent terms 'device,' 'implant,' and 'sustained-release composition' and 'composition' are intended to refer to such polymeric solids. Typically, such sustained-release compositions are formed through the solidification of a liquid precursor described herein as a 'liquid composition.' The sustained-release compositions of the present invention are formulated to contain the antibacterial agent chlorhexidine, most preferably chlorhexidine digluconate. Such sustained-release compositions are preferably specially adapted to permit their introduction into the periodontal pocket (or gingival crevice) of a recipient, or into a dental cavity or hole." (Underlining added.)

Furthermore, column 7, lines 20-23 note that the Friedman material is a non-gel-like material. Therefore, the device of Friedman operates as a solid.

In contrast, Berggren discloses a flowable material for the delivery of drugs. Thus, if one were to incorporate the flowable material of Berggren into Friedman, the principle of operation of Friedman, that is, the use of dried solid implants, would be completely changed.

In summary, it is submitted that Berggren and Friedman do not teach or suggest all of the claim limitations of amended independent claim 1 (and claims 2-10 that depend thereon) or amended independent claim 12 (and claims 13-14 and 16-20 that depend thereon) or amended independent claim 25 (and claims 26-29 that depend thereon). Second, it is believed that the proposed modification of Friedman with Berggren would change the principle of operation of the Friedman device being modified such that the teachings of Friedman and Berggren are not sufficient to render amended independent claim 1 (and claims 2-10 that depend thereon) or amended independent claim 12 (and claims 13-14 and 16-20 that depend thereon) or amended independent claim 25 (and claims 26-29 that depend thereon) *prima facie* obvious.

Miller was cited as teaching peroxides as a cross-linking agent. However, if one were to incorporate the material of Miller into Friedman, the principle of operation of Friedman, that is, the use of dried implants, would be completely changed. Thus, a *prima facie* case of obviousness for amended independent claim 1 (and claims 2-10 that depend thereon) or amended independent claim 12 (and claims 13-14 and 16-20 that depend thereon) or amended independent claim 25 (and claims 26-29 that depend thereon) also cannot be established using Miller.

Higashi was cited a disclosing a periodontal disease treatment comprising atelocollagen and a cross-linking agent. However, looking at Experiment 1 of Higashi, glutaraldehyde is used in forming the Higashi material, and as explained at page 2, lines 28-30 of the present specification, there are problems with using glutaraldehyde. Note that all of independent claims

1, 12, and 25 exclude glutaraldehyde which is cytotoxic. Thus, one would not look to Higashi to make up for the deficiencies in Friedman.

Conclusion

It is believed that in light of the amendments presented and arguments made in this response, the entire application has been placed in condition for allowance.

If any fees are needed, please charge them to Deposit Account 17-0055.

Respectfully submitted,

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